105 CMR 120.000: MASSACHUSETTS REGULATIONS FOR THE CONTROL OF RADIATION (MRCR)

120.001: GENERAL PROVISIONS

120.002: Purpose and Scope

Except as otherwise specifically provided, 105 CMR 120.000 apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in 105 CMR 120.000 shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission (NRC). Regulation by the Commonwealth of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the NRC and to 10 CFR Part 150 of the NRC's regulations.

120.003: Regulatory Authority

The authority for the Department of Public Health to promulgate 105 CMR 120.000 is found in: M.G.L. c. 111, '' 3, 5M, 5N, 5O, 5P.

120.004: Citation

105 CMR 120.000 shall be known and may be cited as the Massachusetts Regulations for the Control of Radiation (MRCR).

120.005: Definitions

As used in 105 CMR 120.000, these terms have the definitions set forth below. Additional definitions used only in a certain Section will be found in that Section.

A_1 means the maximum activity of special form radioactive material permitted in a Type A package. A_2 means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in 120.795: *Table I*, or may be derived in accordance with the procedure prescribed in 120.795: *Appendix A*.

Absorbed dose means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

Accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.

Accelerator-Produced Material means any material made radioactive by a particle accelerator.

Act means M.G.L. c. 111 ' ',3, 5M, 5N, 5O, 5P.

Activity means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

120.005: continued

Adult means an individual 18 or more years of age.

Agency means the Radiation Control Program of the Massachusetts Department of Public Health.

Agreement State means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under ' 274b of the Atomic Energy Act of 1954, as amended (St. 1973, c. 689).

Airborne Radioactive Material means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne radioactivity area means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(a) In excess of the derived air concentrations (DAC>s) specified in 105 CMR 120.200: *Appendix B*, Table I; or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC- hours.

Airline Respirator (see Supplied-Air Respirator (SAR)).

Air-purifying Respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

As low as is reasonably achievable (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in 105 CMR 120.000 as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of ionizing radiation and licensed or registered sources of radiation in the public interest.

Assigned protection factor (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly trained and fitted users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

Atmosphere-supplying Respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SAR=s) and self-contained breathing apparatus (SCBA) units.

Background radiation means radiation from cosmic sources;, non-technologically enhanced naturally occurring radioactive material, including radon, except as a decay product of source or special nuclear

material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Agency.

Becquerel (Bq) means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).

Bioassay means the determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting), or by analysis and evaluation of materials excreted or removed from the human body. For purposes of 105 CMR 120.000, "radiobioassay" is an equivalent term.

Brachytherapy means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

Byproduct material means:

(1) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

Calendar quarter means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. The method observed by the licensee or registrant for determining calendar quarters shall only be changed at the beginning of a year.

Calibration means the determination of:

(1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(2) the strength of a source of radiation relative to a standard.

CMR means Code of Massachusetts Regulations.

CFR means Code of Federal Regulations.

Chelating agent means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

Collective dose means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Committed dose equivalent ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Commissioner means the Commissioner, Massachusetts Department of Public Health.

Committed effective dose equivalent ($H_{E,50}$) means the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma\ w_T H_{T,50}$).

Confirmatory Action Letters means letters, confirming a licensee=s, registrant=s, or vendor=s agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

Constraint (dose constraint) means a value above which specified licensee actions are required.

Critical group means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

Curie means a unit of quantity of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} "disintegrations or transformations per second (dps or tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 1×10^{-3} curie = 3.7×10^{7} tps. One microcurie (μCi) = 1×10^{-6} curie = 3.7×10^{4} tps. One nanocurie (nCi) = 1×10^{-9} curie = 3.7×10^{1} tps. One picocurie (pCi) = 1×10^{-12} curie = 10^{-2} tps.

Decommission means to remove safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and/or termination of license.

Deep dose equivalent (H_d) means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2) and applies to external whole body exposure.

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the face piece only when a negative pressure is created inside the facepiece by inhalation

Department means the Department of Public Health.

Depleted Uranium means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

Disposable respirator means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or

a disposable escape-only self-contained breathing apparatus (SCBA).

Distinguishable from background means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

Dose is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of 105 CMR 120.000, "radiation dose" is an equivalent term.

Dose equivalent (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

Dose limits means the permissible upper bounds of radiation doses established in accordance with 105 CMR 120.000. For purposes of 105 CMR 120.000, "limits" is an equivalent term.

Effective dose equivalent (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma\, w_T H_T$).

Embryo/fetus means the developing human organism from conception until the time of birth.

Entrance or access point means any ~~opening~~ location through which an individual ~~or extremity of an individual~~ could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Explosive material means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

Exposure means being exposed to ionizing radiation or to radioactive material.

Exposure means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). See 105 CMR 120.013 Units of Exposure and Dose for the special unit.

Exposure Rate means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

External Dose means that portion of the dose equivalent received from any source of radiation outside the body.

Extremity means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

~~Eye Dose Equivalent means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).~~

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test means the use of a protocol to qualitatively evaluate the fit of a respirator on an individual.

Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) Licensed Facilities means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

Generally Applicable Environmental Radiation Standards means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Gray (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

Half-value layer (HVL) means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

Hazardous Waste means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

Healing Arts means any discipline which involves the diagnosis or treatment of persons by a practitioner or animals by a veterinarian, and who is licensed for that purpose by the Commonwealth of Massachusetts, and which discipline includes the intentional exposure of persons and animals to sources of radiation for diagnosis or treatment.

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High Radiation Area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Human Use means the internal or external administration of radiation or radioactive material to human beings.

Individual means any human being.

Individual monitoring means the assessment of:

(1) Dose equivalent.
  (a) by the use of individual monitoring devices; or
  (b) by the use of survey data; or
(2) Committed effective dose equivalent.
  (a) by bioassay; or
  (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. (*See* the definition of DAC-hours in 105 CMR 120.200).

Individual monitoring devices means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of 105 CMR 120.000, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescence (OSL) dosimeters, and personal (lapel) air sampling devices.

Inspection means an official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Agency.

Instrument Traceability means the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at laboratory accredited by a program, which requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology, or other equivalent national or international program.

~~Internal dose means that portion of the dose equivalent received from radioactive material taken into the body.~~

Interlock means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

Internal dose means that portion of the dose equivalent received from radioactive material taken into the body.

Ionizing Radiation (*See* Radiation).

Irradiation means the exposure of a living being or matter to ionizing radiation.

Kilovolt (kV) [kilo electron volt (keV)] means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons.]

Lead Equivalent means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

Leakage Radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

(1) The useful beam; and,
(2) Radiation produced when the exposure switch or timer is not activated.

Lens dose equivalent (LDE) means the external exposure to the lens of the eye as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

License means a license issued by the Agency in accordance with the regulations adopted by the Agency.

Licensed (or registered) material means radioactive material received, possessed, used, transferred or disposed of under a general or specific license [or registration] issued by the Agency.

Licensee means any person who is licensed by the Agency in accordance with 105 CMR 120.000 and M.G.L. c. 111, '' 3, 5M, 5N, 5O and 5P.

Licensing State means any State, which has been finally designated as such by the Conference of Radiation Control Program Directors, Inc., which reviews state regulations to establish equivalency with the Suggested State Regulations and ascertains whether a State has an effective program for control of natural occurring or accelerator produced radioactive material (NARM). The Conference will designate as Licensing States those states with regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM. ~~with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.~~

Limits (*See* Dose limits).

Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Lost or missing source of radiation means licensed [or registered] source of radiation whose location is unknown. This definition includes, but is not limited to, licensed (or registered) material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

Major Processor means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in 105 CMR 120.772.

Manifest means a detailed record of the characteristics and quantities of packaged waste as presented for transportation, treatment, storage, or disposal which usually accompanies waste transfers for these purposes.

Member of the public means an individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.

Monitoring means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of 105 CMR 120.000, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

NARM means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

Natural Radioactivity means radioactivity of naturally occurring nuclides.

Non-ionizing Radiation (*See* Radiation).

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

NORM means any naturally occurring radioactive material. It does not include accelerator produced, byproduct, source, or special nuclear material.

Nuclear Regulatory Commission (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

Occupational dose means the dose received by an individual in the course of employment in which the

individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, or from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 105 CMR 120.527, ~~as a patient from medical practices,~~ or from voluntary participation in medical research program, or as a member of the public.

Package means the packaging together with its radioactive contents as presented for transport.

Particle accelerator (*See* Accelerator).

Patient means an individual subjected to healing arts examination, diagnosis, or treatment

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of the commonwealth other than the department, any political subdivision of the commonwealth, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but not including federal government agencies.

Personnel monitoring equipment (*See* Individual monitoring devices).

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

Pharmacist means an individual certified as such under M.G.L. c. 112, ' 24 to compound and dispense drugs, prescriptions, and poisons.

Physician means an individual certified as a physician under M.G.L. c. 112, ' 2 or corresponding citation of earlier laws.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Principal Activities means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Protective Apron means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

Protective Barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(1) Primary protective barrier means the material, excluding filters, placed in the useful beam.

(2) Secondary protective barrier means the material which attenuates stray radiation.

Public dose means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant ~~sources of radiation licensed or registered operations~~. Public dose does not include occupational dose, or doses received from background radiation,from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 105 CMR 120.540, or ~~or dose received as a patient from medical practice, or dose~~ from voluntary participation in medical research programs.

Pyrophoric Material means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C) or any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

Qualified expert means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

Qualitative fit test (QLFT) means a pass/f~~f~~ail fit test to assess the adequacy of respirator fit that relies on the individual~~'~~s response to the test agent.

Quality factor (Q) means the modifying factor, listed in 105 CMR 120.014: Tables I and II, that is used to derive dose equivalent from absorbed dose.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Rad means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

Radiation means alpha particles, beta particles, gamma rays, x rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of 105 CMR 120.000, ionizing radiation is an equivalent term. Radiation, as used in 105 CMR 120.000, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

Radiation area means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Radiation dose (*See* Dose).

Radiation Detector means a device which, in the presence of radiation, provides by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation machine means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

Radiation Safety Officer means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and programs ~~; and who is identified on a certificate of registration or radioactive material license as the Radiation Safety Officer.~~ and has been assigned such responsibility by the licensee or registrant.

Radioactive Material means any solid, liquid, or gas which emits radiation spontaneously.

Radioactivity means the transformation of unstable atomic nuclei with the emission of radiation.

Radiobioassay (*See* Bioassay).

Registrant means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to 105 CMR 120.000 and M.G.L. c. 111, '' 3, 5M, 5N, 5O, and 5P.

Registration means registration with the Agency in accordance with the regulations adopted by the Agency.

Regulations of the U.S. Department of Transportation (U.S. DOT), means the regulations in 49 CFR Parts 100-189.

Rem means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

Research and Development means:

(1) theoretical analysis, exploration, or experimentation; or

(2) the extension of investigative findings and theories of a scientific or technical nature into

practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee=s control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 105 CMR 120.200.

Restricted area means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Roentgen means the special unit of exposure. One roentgen (R) equals 2.58 x 10^{-4} coulombs/kilogram of air (*see* Exposure).

Scattered radiation means ionizing radiation emitted by the interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

Scattered primary radiation means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam.

Sealed Source means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Sealed Source and Device Registry (SSD) means the national registry that contains the registration certificates, maintained by the Nuclear Regulatory Commission (NRC), that summarize the radiation safety information for sealed sources and devices, and describe the licensing and use conditions approved for the product.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Shallow dose equivalent (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2). ~~averaged over an area of 1 square centimeter.~~

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
SI means the abbreviation for the International System of Units.

Sievert means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

Site boundary means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

Source Material means:

(1) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(2) ores which contain by weight 1/20 of 0.05% or more of:

(a) uranium;

(b) thorium; or

(c) any combination thereof.

Source material does not include special nuclear material.

Source Material Milling means any activity that results in the production of byproduct material as defined by definition (2) of byproduct material.

Source of Radiation, means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

Source Traceability means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology (NIST), or by a laboratory which participates in a continuing measurement quality assurance program with NIST or other equivalent national or international program.

Special form radioactive material means radioactive material which satisfies the following conditions:

(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(2) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

(3) It satisfies the test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

Special nuclear material means:

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other

material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

Special Nuclear Material in Quantities not Sufficient to Form a Critical Mass means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium- 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or presence of sources of radiation . When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

Test means the process of verifying compliance with an applicable regulation.
105 CMR 120.000 means all Sections of the Massachusetts Regulations for the Control of Radiation.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face

Total effective dose equivalent (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

Total organ dose equivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 105 CMR 120.267(A)(6).

Traceable to National Standard (*See* Instrument Traceability or Source Traceability]

U.S. Department of Energy means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 *et seq.*, to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law

95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

User seal check (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Unrefined and Unprocessed Ore means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

Unrestricted Area (Uncontrolled Area) means area access to which is neither limited nor controlled by the licensee or registrant. For purposes of 105 CMR 120.000, uncontrolled area is an equivalent term.

Vendor means a supplier of products or services to be used by a licensee or registrant or a licensed or registered facility or activity.

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates [Note: At very high dosee rates, units of adsorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem].

Waste means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (a) not classified as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (a) by the NRC.

Waste Handling Licensees means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

Week means seven consecutive days starting on Sunday.

Whole body means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

Worker means an individual engaged in ~~work~~ activities under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

Working level (WL) means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

Working level month (WLM) means an exposure to one working level for 170 hours - 2,000 working

hours per year divided by 12 months per year is approximately equal to 170 hours per month.

Year means the period of time beginning in January used to determine compliance with the provisions of 105 CMR 120.000. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

120.006: Exemptions

(A) General Provision. The Agency may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of 105 CMR 120.000 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(B) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this Commonwealth is exempt from 105 CMR 120.000 to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or Government-controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

(3) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and,

(4) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine:

(a) That the exemption of the prime contractor or subcontractor is authorized by law; and,

(b) That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

120.007: Prohibited Uses

(A) A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

(B) A Shoe-fitting fluoroscopic device shall not be used.

120.008: Impounding

Sources of radiation shall be subject to impounding pursuant to M.G.L. c. 111, '' 5O and 5P.

120.009: Records

(A) Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in 105 CMR 120.000.

(B) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Agency:

(1) Records of disposal of licensed material made under 105 CMR 120.252 (including burials authorized before January 28, 1981), 105 CMR 120.253, 120.254,120.255; and,

(2) Records required by 105 CMR 120.263(B)(4).

(C) If licensed activities are transferred or assigned in accordance with 105 CMR 120.131(B), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

120.009: continued

(1) Records of disposal of licensed material made under 105 CMR 120.252 (including burials authorized before January 28, 1981), 105 CMR 120.253, 120.254,120.255; and,
(2) Records required by 105 CMR 120.263(B)(4).

(D) Prior to license termination, each licensee shall forward the records required by 105 CMR 120.125(C)(1)(g) to the Agency.

120.010: Inspections

(A) Each licensee and registrant shall afford the Agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

(B) Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to 105 CMR 120.000.

120.011: Tests

Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform, such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

(A) Sources of radiation;

(B) Facilities wherein sources of radiation are used or stored;

(C) Radiation detection and monitoring instruments; and,

(D) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

120.012: Additional Requirements

The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in 105 CMR 120.000 as it deems appropriate or necessary to minimize danger to public health and safety or property.

120.013: Communications

All correspondence in compliance with 105 CMR 120.000 shall be ~~, and applications filed thereunder, should be addressed to the~~sent to the Department of Public Health, Radiation Control Program, at the ~~program's~~ current mailing address ~~Agency at its office located at 174 Portland Street, Boston, MA,~~

~~02114~~.

120.014: Units of Exposure and Dose

(A) As used in 105 CMR 120.000, the unit of Exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to 2.58 x 10^{-4} coulomb per kilogram of air.

(B) As used in 105 CMR 120.000, the units of dose are:

Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rads).

Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 sievert = 100 rems).

120.014: continued

(C) As used in 105 CMR 120.000, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

(D) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 105 CMR 120.014(C), 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of 105 CMR 120.000, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

*Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

120.014: continued

TABLE II
MEAN QUALITY FACT0RS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor* (Q)	Fluence per Unit Dose Equivalent** (neutrons cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent** (neutrons cm^{-2} Sv^{-1})
(thermal)	2.5×10^{-8}	2	980×10^{6}	980×10^{8}
	1.0×10^{-7}	2	980×10^{6}	980×10^{8}
	1.0×10^{-6}	2	810×10^{6}	810×10^{8}
	1.0×10^{-5}	2	810×10^{6}	810×10^{8}
	1.0×10^{-4}	2	840×10^{6}	840×10^{8}
	1.0×10^{-3}	2	980×10^{6}	980×10^{8}
	1.0×10^{-2}	2.5	1010×10^{6}	1010×10^{8}
	1.0×10^{-1}	7.5	170×10^{6}	170×10^{8}
	5.0×10^{-1}	11	39×10^{6}	39×10^{8}
	1	11	27×10^{6}	27×10^{8}
	2.5	9	29×10^{6}	29×10^{8}
	5	8	23×10^{6}	23×10^{8}
	7	7	24×10^{6}	24×10^{8}
	10	6.5	24×10^{6}	24×10^{8}
	14	7.5	17×10^{6}	17×10^{8}
	20	8	16×10^{6}	16×10^{8}
	40	7	14×10^{6}	14×10^{8}
	60	5.5	16×10^{6}	16×10^{8}
	1.0×10^{2}	4	20×10^{6}	20×10^{8}
	2.0×10^{2}	3.5	19×10^{6}	19×10^{8}
	3.0×10^{2}	3.5	16×10^{6}	16×10^{8}
	4.0×10^{2}	3.5	14×10^{6}	14×10^{8}

120.015: Units of Activity

For purposes of 105 CMR 120.000, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

* Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

** Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

(A) One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps).

(B) One curie (Ci) = 3.7×10^{10} disintegrations or transformations per second (dps or tps) = 3.7×10^{10} becquerel (Bq) = 2.22×10^{12} disintegrations or transformations per minute (dpm or tpm).

120.016: Enforcement ~~Policy and Procedures~~

(A) ~~Enforcement Policy~~Purpose. The purpose of the enforcement program of the Agency is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:

(1) Ensuring compliance with regulations and conditions of license;

(2) Obtaining prompt correction of violations ~~and adverse quality conditions which~~that may affect safety;

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(3) Deterring future violations ~~and occurrences of conditions adverse to quality~~; and,

(4) Encouraging improvement of licensee, registrant and vendor performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with all persons who do not comply with regulations. In no case will licensees who do not achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

(B) Grounds for Immediate Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease Activity. In accordance with M.G.L. c. 111, ' 5O, the Commissioner may summarily suspend a license or certificate of registration or order immediate cessation of an activity, without a prior hearing, whenever the Department finds that public health, safety or the environment would be threatened by delay in issuance of an order. A facility or person may not operate during the period of a suspension of his/its license or certificate of registration and may not conduct a prohibited activity after notification of an order requiring the immediate cessation of an activity. However, upon request by the licensee or registrant, a hearing shall be provided promptly after the issuance of such suspension or order.

(C) Grounds for Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration.

(1) Specific Grounds. The Department may issue an order denying, revoking, modifying, limiting, or refusing to renew a license or certificate of registration sought or issued under 105 CMR 120.000 for any one of the following reasons:

(a) The applicant, licensee or registrant has failed to submit the information required for licensure or registration under 105 CMR 120.000.

(b) The applicant failed to meet the requirements for licensure or registration as specified in 105 CMR 120.000.

(c) The applicant, licensee or registrant is not suitable and responsible to operate a facility as required or provide the service as licensed or registered.

(d) The applicant, licensee or registrant has obtained or attempted to obtain or maintain a certificate of registration or license by fraud, misrepresentation, or by the submission of incorrect, false or misleading information.

(e) The applicant, licensee or registrant has failed to pay licensure and/or registration fees.

(f) The applicant, licensee or registrant has failed to pay civil penalties or criminal fines levied in accordance with of M.G.L. c. 111, ' 5O or ' 5P and/or 105 CMR 120.000.

(g) The applicant, licensee or registrant has:

1. failed to allow duly authorized agents of the Agency to conduct inspections; or

2. attempted to impede the work of duly authorized representatives of the Agency or the enforcement of any provisions of M.G.L. c. 111 '' 5N through P or 105 CMR 120.000.

(h) The applicant, licensee or registrant has been convicted of, pleaded guilty to, or has, in a judicial proceeding, admitted facts sufficient for a finding that he/she is guilty of, any criminal violation relating directly or indirectly to his/her fitness to be licensed or registered under 105

CMR 120.000.

(i) The applicant, licensee or registrant has been the subject of proceedings which resulted in the suspension, denial, modification, limitation, or revocation of a similar license or certificate of registration or refusal of renewal of a similar license.

(j) The applicant, licensee or registrant has been the subject of proceedings which were ultimately resolved by settlement agreement but which were initiated to suspend, deny, modify, limit, or revoke or refuse renewal of a license, unless the Settlement Agreement contained provisions which either:

a. stated that the licensee, applicant or registrant was not guilty of the violations he/she/it was charged with or

b. provided that the charges or violations that were the subject of the Settlement Agreement or the Settlement Agreement itself cannot be used in whole or in part as the basis for any future licensing, registration or enforcement action by the Department.

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(k) The applicant, licensee or registrant has been disciplined in another jurisdiction in any way by a licensing authority for reasons substantially the same as those set forth herein.

(l) The applicant or licensee operated a facility after the expiration of the license.

(m) The applicant, licensee or registrant has failed to remedy or correct a cited violation by the date specified in the written notice from the Department under M.G.L. c. 111, ' 5O or by the date specified in the plan of correction accepted or modified by the Department, unless the applicant, licensee or registrant demonstrates to the satisfaction of the Department that such failure was not due to neglect of duty and occurred despite his/her good faith attempt to make corrections by the specified time.

(n) The applicant or licensee has engaged in or aided in the falsification of test results or any other records required to be maintained in accordance with 105 CMR 120.000.

(o) The applicant, licensee or registrant receives, possesses, uses, transfers, owns or operates or uses radioactive materials or machines which emit ionizing radiation in a manner which endangers public health, safety, or the environment.

(2) Other Grounds The Department reserves the right to deny, modify, limit revoke or refuse to renew~~view~~ a license or certificate of registration for any other sufficient reason not listed in 105 CMR 120.016(C)(1) if it reasonably considers such action necessary to protect the public health, safety or the environment. In addition, nothing herein shall be deemed to limit the Department's authority to establish or recognize further general or specific grounds for discipline through rulemaking, adjudication, the issuance of policies or advisories or other similar means.

(D) Severity of Violations.

(1) ~~Regulatory requirements have varying degrees of safety or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.~~ Violations of 105 CMR 120.000 are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:

(a) Health Physics;

(b) Transportation;

(c) Materials Operations;

(d) Miscellaneous Matters; and,

(e) Emergency Preparedness.

(2) Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V to those that are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; *i.e.* if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

(3) Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in Health Physics is not directly comparable to that associated with Severity Level I violations in Emergency

Preparedness.

(4) While examples are provided in 105 CMR 120.019: *Appendix A* for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each of the examples is predicated on a violation of an existing regulatory requirement. Each is designed to illustrate the significance which the Department places on a particular type of violation of regulatory requirements.

(5) In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

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(6) The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indication of willfulness. The term "willfulness" includes, but is not limited to, the deliberate violation of any provision of M.G.L. c. 111, '' 3, 5M, 5N, 5O, and 5P or careless disregard of the requirements of M.G.L. c. 111, '' 3, 5M, 5N, 5O, and 5P. Willfulness does not include acts which do not rise to the level of careless disregard, *e.g.* inadvertent clerical errors in a document submitted to the Agency. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (*e.g.*, first-line supervisor or senior manager), the significance or any underlying violation, the intent of the violator (*i.e.* negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

(7) The Agency expects licensees to provide complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in 105 CMR 120.019: *Appendix A* the severity level of a violation involving the failure to make a required report to the Agency will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event which it failed to report or should have been aware of the condition or event. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

~~(8)~~(E) Enforcement Conference. Whenever the Agency has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, or recurring nonconformance on the part of a vendor, the Agency may schedule an enforcement conference with the licensee or vendor prior to taking enforcement action. The Agency may also elect to hold an enforcement conference for other violations, e.g. Severity Level IV violation which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to:

(a) Discuss the violations or nonconformance, their significance and causes, and the licensee's or vendor's corrective actions;

(b) Determine whether there are any aggravating or mitigating circumstances;

(c) Obtain other information which will help determine the appropriate enforcement action; and,

(d) Provide an opportunity for the licensee to explain what corrective actions have been taken or will be taken in response to the Notice of Violation.

~~(9) In addition, during the enforcement conference, the licensee or vendor will be given an opportunity to explain to the Agency what corrective actions (if any) were taken or will be taken~~

~~following discovery of the potential violation or nonconformance. Licensees or vendors will be told when a meeting is an enforcement conference.~~

~~(10) When needed to protect the public health and safety, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, or revoking a license, will be taken prior to the enforcement conference. In such cases, an enforcement conference may be held after the escalated enforcement action is taken~~

(F~~E~~) Enforcement Procedures.

(1)(a) Notice of Violation. Whenever the Agency finds upon inspection, investigation of a complaint or through information in its possession that an applicant, licensee or registrant is not in compliance with provisions of M.G.L. c. 111, '' 5N through 5P or a regulation promulgated thereunder, the Agency shall notify the applicant, licensee or registrant of such violation or deficiency. The notice shall include a statement of the violations or deficiencies found, the provision of the law relied upon, and a reasonable period of time for correction. A violation or deficiency may result in denial, suspension, revocation or refusal to renew a license or certificate of registration; a modification or limitation of a license or certificate of registration; a cease and desist order; and/or the imposition of a civil penalty and/or criminal sanctions.

(b) Confirmatory Action Letters. The Agency may issue Confirmatory Action Letters confirming a licensee's, registrant's, or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

(2) Plan of Correction.

(a) The applicant, licensee or registrant shall, within ten days of receipt of the notice, file with the Agency a written plan of correction. The plan shall clearly identify the licensee or registrant, state the date, reference the violation(s) ~~or deficiency~~ cited, state specific corrective action(s) and timetable(s) and date(s) for completion for each ~~deficiency~~ violation cited, and shall be signed by either the applicant, licensee or registrant or his/her designee.

(b) The Agency may re-inspect a facility in order to determine whether the corrections have been made. If upon review of a plan of correction and/or reinspection the Agency finds that the applicant, licensee or registrant is in compliance with 105 CMR 120.000 and~~/or~~ that the applicant, licensee or registrant has submitted an acceptable plan of correction, the Agency shall notify the applicant, licensee or registrant of its findings of compliance and~~/or~~ its acceptance or modification of the plan of correction.

(c) If upon review of plan of correction and/or reinspection the Agency finds the plan of correction is unacceptable, the Agency may request that the applicant, licensee or registrant amend and resubmit the plan of correction within five days of the date of notice of the required amendment to the plan of correction or such other time as the Agency may specify for resubmission.

(d) If upon review of the plan of correction and/or reinspection the Agency determines that an applicant, licensee or registrant remains non-compliant with applicable laws and regulations regarding licensure, or the Agency determines that further enforcement action is necessary to ensure compliance with regulatory requirements and deter future non-compliance, the Department may initiate enforcement procedures as set forth below.

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(3) Notice of Department's Intent to Issue an Order.

(a) Except as specified in 105 CMR 120.016(F)(4)(b), ~~P~~prior to the Department issuing an order to modify, limit, deny, revoke or refuse to renew a license, and/or to require a person to cease and desist any activity, and/or to impose civil penalties, the applicant, licensee or registrant shall be notified in writing of the Agency~~'~~s Intent to Issue an Order. The Notice of Intent to Issue an Order shall include the grounds for the Department's action, the provision(s) of law relied upon, the amount of any civil penalty or the requirements of the proposed order, and ~~his/her~~a right to request an adjudicatory ~~proceeding and/or judicial review~~hearing.

(b) If a license or certificate of registration is to be denied, modified, limited, revoked or refused renewal or if an activity is to be ceased or a civil penalty imposed by the Department, then the aggrieved applicant, licensee or registrant may request an adjudicatory hearing within 21 days of receipt of notification of the Department's Intent to Issue an Order. Said request shall be filed in accordance with Standard Adjudicatory Rules of Practice and Procedures, 801 CMR 1.01 *et seq*.

(4) Administrative Hearings: Procedure.

(a) Immediate Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease an Activity:

1. The Department shall give the licensee or registrant written notice stating the reason(s) for the immediate suspension or issuance of an order to immediately cease an activity and the provisions of law relied upon. The immediate suspension or order to immediately cease an activity shall take effect immediately upon issuance of the notice.

2. The Department shall provide for a hearing pursuant to 80l CMR 1.01 *et seq*. promptly after the issuance of an order of immediate suspension or an order to immediately cease an activity.

3. In cases of immediate suspension of a license or certificate of registration or issuance of an order to immediately cease an activity, the Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that there existed, immediately prior to or at the time of the immediate suspension or cease and desist order, a threat to public health, safety or the environment.

4. In the event that the Department determines that the violation of state law or of 105 CMR 120.000 which posed a threat to public health, safety or the environment is corrected prior to the decision of the Hearing Officer, the Department may lift the immediate suspension by giving written notice to the licensee or registrant.

(b) Denial, Modification, Limitation, Revocation, or Refusal to Renew a License or Certificate of Registration Based on Failure to File Reports or Pay Fees or Maintain Insurance: In accordance with M.G.L. c.30A, '13, no Notice of Intent to Issue an Order shall be required and ~~N~~no hearing shall be ~~afforded~~ offered where denial, modification, limitation, revocation, suspension or refusal to renew~~view~~ is based solely upon failure of the licensee or registrant to file timely reports, schedules or applications, or to pay lawfully prescribed fees, or to maintain insurance coverage as required by any law or regulation.

(c) Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate

of Registration; Orders to Cease an Activity; Civil Penalties:

1. All adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 *et seq*.

2. Except for circumstances specified in 105 CMR 120.016(F~~E~~)(4)(b), if the Department determines that a license or certificate of registration should be denied, modified, limited, revoked, or refused renewal, and/or that a facility should cease an activity, and/or that a civil penalty should be imposed, and if the Department notifies the applicant, licensee or registrant of its intended action, upon receipt of a Notice of Claim for an Adjudicatory Proceeding, the Department shall initiate a hearing pursuant to 801 CMR 1.01 *et seq*.

3. The Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that the license or certificate of registration should be denied, modified, limited, revoked or refused renewal; that an activity should be ceased; and/or that a civil penalty be imposed based on relevant facts as they existed at or prior to the time the Department initiated the hearing procedure.

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4. If the Hearing Officer finds any single ground for denial, modification, limitation, revocation, suspension, or refusal to renew a license or certificate of registration; for a cessation of an activity; and/or for imposition of a civil penalty, then the Hearing Officer shall render a recommended decision affirming the issuance of the Department's Order.

(d) Public Health Council and Judicial Review:

1. The recommended decision of a Hearing Officer in any adjudicatory proceeding conducted under 105 CMR 120.000 shall be reviewed by the Commissioner and the Public Health Council. Their decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A ' 14.

2. Any applicant, licensee or registrant that fails to exercise its right to an adjudicatory proceeding under 105 CMR 120.000 waives ~~both~~ its right to an adjudicatory hearing, its right to administrative review by the Commissioner and the Public Health Council and its right to judicial review pursuant to M.G.L. c. 30A ' 14.

(F) Civil Penalties.

(1) If the Department determines, after a notice has been issued and an opportunity for a hearing has been provided, that a licensee, registrant or vendor has not complied with an order issued pursuant to M.G.L. c. 111 ' 5O or with any provision of M.G.L. c. 111 '' 5N through 5P or with any applicable rule, regulation, license or certificate of registration adopted or issued thereunder, the Department, in lieu of, or in addition to suspending, denying, modifying, limiting, revoking, or refusing renewal of a license or certificate of registration, may assess civil penalties in an amount not exceeding $100,000 per violation. Such civil penalty may be assessed whether or not the violation was willful.

(2) The decision whether to issue a civil penalty and the amount of any civil penalty depends on the facts of each case. Generally, civil penalties are most likely to be imposed for Severity Level I violations and if mitigating circumstances are absent, for Severity Level II violations. Civil penalties are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar to previous violations that occurred after the date of the last inspection or within two years, whichever period is greater, for which the licensee did not take effective corrective action.

~~(3) In applying this guidance for Severity Level IV violations, the Agency normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.~~

(3~~4~~) Civil penalties ~~will normally~~may be assessed for known and conscious violations of the reporting requirements of 105 CMR 120.000 and for any willful violation of any Agency requirement including those at any severity level.

(4~~5~~) Payment of civil penalties imposed under M.G.L. c. 111, ' 5O shall be made by check, draft, or money order payable to the Commonwealth of Massachusetts, and mailed to: the Radiation Control Program~~, 174 Portland Street, Boston, MA 02114~~.

(5~~6~~) Factors in Determining the Amount of Penalty. In determining the amount of the civil penalty, the Department shall consider the following:

(a) The willfulness of the violation;

(b) The actual and potential danger to the public health or the environment;

(c) The actual or potential costs of such danger to the public health or the environment;
(d) The actual or potential damage or injury to the public health or environment;
(e) The actual and potential cost of such damage or injury;
(f) The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 120.000;
(g) Whether the person being assessed the civil penalty did everything reasonable to prevent failure to, to come into compliance promptly, and to remedy and mitigate whatever harm might have been done as a result of the failure to comply;
(h) Whether the person being assessed the civil penalty has previously failed to comply with any order issued pursuant to M.G.L. c. 111, '' 5N through 5P or any rule or regulation adopted hereunder;
(i) Whether imposition of a civil penalty is likely to deter future non-compliance;
(j) The financial condition of the person being assessed the civil penalty; and,
(k) The public interest.

120.016: continued

(G) Escalation of Enforcement Sanctions.

(1) The Department considers violations of Severity Levels I, II or III to be of significant regulatory concern. If ~~serious~~ Severity Level I, II or III violations occur, the Department will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Department carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in 105 CMR 120.016(D).

(2) ~~Normally, t~~The progression of enforcement actions for similar violations will usually be based on similar violations at an individual facility and not on similar violations under the same license. However, ~~it should be noted that~~ under some circumstances~~;~~ (*e.g.*, where there is common control over some facet of facility operations), similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a health physics violation at one division of a dual unit hospital that repeats an earlier violation of the other division might be considered similar.

(H) Criminal Enforcement. The Department may elect to enforce any section of ~~the regulations~~105 CMR 120.000 or provision of M.G.L. c. 111, ' 5P by seeking to have criminal sanctions imposed. Any person who violates M.G.L. c. 111, ' 5N or ' 5O or any rule, regulation, license, registration, or order adopted or issued under said M.G.L. c. 111, ' 5N or ' 5O shall be fined not less than $100 nor more than $2,000, or be imprisoned for a period of not more than two years, or both. Any person who continues to violate the provisions of the aforementioned laws after due notice by the Department shall be fined not less than $1,000 nor more than $20,000 or be imprisoned for a period of not more than 20 years, or both. After due notice has been issued by the Department, each day of such violation shall constitute a separate offense.

(I) Judicial Enforcement. The Department may apply directly to the Supreme Judicial Court or Superior Court to enforce any provision of M.G.L. c. 111, '' 5N through 5P and/or any rule or regulation, license, registration, or order adopted and issued thereunder by the Department. When a person is engaged in or about to engage in any act or practice which constitutes or will constitute a violation of such provision, rule, regulation, license, registration, or order, the Department may seek to restrain such act or practice or the use or occupation of premises or parts thereof or such other equitable relief as public health and safety requires.

(J) Nonexclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 120.000 are mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

(K) Deliberate Misconduct.

(1) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or

certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, may not:

(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Agency; or

(b) Deliberately submit to the Agency, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

(2) A person who violates 105 CMR 120.016(K) (1)(a) or (1)(b) may be subject to enforcement action in accordance with the procedures in 105 CMR 120.016.

(3) For the purposes of 105 CMR 120.016(K) (1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Agency; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

120.017: Severability

The provisions of 105 CMR 120.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

120.018: Public Disclosure of Enforcement Actions

In accordance with M.G.L. c. 30A, the Administrative Procedures Act, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases ~~are generally~~may be issued for civil penalties related to violations at Severity Level I, II, or III. ~~Press releases are issued at the time of the order or the proposed imposition of the civil penalty.~~

120.019: Appendix A -- Severity Categories

The following examples of severity levels are neither exhaustive nor controlling. They reflect only

the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

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(A) Severity Level 1 -- Most Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands or forearms;

(b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 105 CMR 120.253;

(d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 105 CMR 120.253;

(e) Exposure of a worker in restricted areas of ten times the limits of 105 CMR 120.212.

(2) Transportation.

(a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or,

(b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the Agency limits.

(3) Materials Operations.

(a) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;

(b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

(4) Miscellaneous Matters.

(a) A Material False Statement (MFS)[1] in which the statement made was deliberately false;

(b) Falsification of records which the Agency requires be kept of significant information in which the records were deliberately falsified by or with the knowledge of management; or,

(c) A knowing and intentional failure to provide any notice required by 105 CMR 120.000.

(d) Possession of licensable quantities of radioactive material without a license, or loss of control of a source of radiation.

(e) Refusing authorized Agency personnel access to facilities, records and/or equipment to conduct inspections or investigations.

(5) Emergency Preparedness. In an emergency, licensee failure to promptly:

(a) correctly identify the event;

(b) make required notifications to responsible Federal, State, and local agencies; or

(c) respond to the event (*e.g.*, assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

(B) Severity Level II -- Very Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body or 75 rems to the feet, ankles, hands or forearms;

(b) Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of five times the limits of

105 CMR 120.222;

(d) Failure to make an immediate notification as required by 105 CMR 120.282(A), and (B);

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[1] In essence, a Material False Statement is a statement that is false by omission or commission and is relevant to the regulatory process. As can be seen in the examples, in determining the specific severity level of a violation involving material false statements or falsification of records, consideration will be given to such factors as the position of the person involved in the violation (*e.g.*, first line supervisor or senior manager), the significance of the information involved, and the intent of the violator (*i.e.*, negligence not amounting to careless disregard or deliberateness). The relative weight given to each of these factors will be dependent on the circumstances of the violation.

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(e) Disposal of license material in quantities or concentrations in excess of five times the limits of 105 CMR 120.253;

(f) Exposure of a worker in restricted areas in excess of five times the limits of 105 CMR 120.212.

(g) An x-ray system having a malfunction such that inadvertent exposures could occur *e.g.*, a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.

(h) A fluoroscopic x-ray system with a tabletop entrance exposure rate of greater than or equal to 25 R/min. at the point where the center of the useful beam enters the patient, except:

a. During recording of fluoroscopic images; or,

b. When an optional high level control is activated.

(i) A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier; or,

(j) Therapy systems which exhibit excessive leakage and/or inoperable door interlocks, shutters, timers, *etc*.

(k) Therapy system, with improper operator/patient communication/observation.

(2) Transportation.

(a) Breach of package integrity resulting in surface contamination or external radiation levels in excess of Agency requirements;

(b) Surface contamination or external radiation levels in excess of five times Agency limits that did not result from a breach of package integrity; or,

(c) Failure to make required initial notifications associated with Severity Level I or II violations.

(3) Material Operations.

(a) Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or,

(b) A system designed to prevent or mitigate a serious safety event being inoperable.

(4) Miscellaneous Matters.

(a) A MFS, or a reporting failure, involving information which, had it been available to the Agency and accurate at the time the information should have been submitted, would have resulted in regulatory action or would likely have resulted in the Agency seeking further information;

(b) A MFS in which the false statement was made with careless disregard.

(c) Deliberate falsification of records which the Agency requires be kept involving significant information; or,

(d) A failure to provide the notice required.

(e) Failure to register sources of radiation or services as required by 105 CMR 120.000.

(f) Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Agency.

(5) Emergency Preparedness. Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

(C) Severity Level III --- Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms;

(b) A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one hour period or 500 millirem in a seven consecutive days;

(c) Failure to make a 24-hour notification as required by 105 CMR 120.281 or an immediate notification required by 105 CMR 120.282;

(d) Substantial potential for an exposure or release in excess of 105 CMR 120.200, whether or not such exposure or release occurs (*e.g.*, entry into high radiation areas, such as under reactor vessels or in the vicinity of exposed radiographic sources, without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);

(e) Release of radioactive material to an unrestricted area in excess of the limits of 105 CMR 120.222;

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(f) Improper disposal of licensed material not covered in Severity Level I or II;

(g) Exposure of worker in restricted areas in excess of the limits of 105 CMR 120.212;

(h) Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program;

(i) Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;

(j) Conduct of licensee activities by a technically unqualified person;

(k) Significant failure to control licensed material;

(l) Failure to use exposure reduction devices properly (*e.g.*, collimators, filtration);

(m) For a fluoroscopic system where the maximum allowable tabletop exposure rate is 5 R/min., test values of greater than or equal to 7 R/min. (uncorrected), but less than 25 R/min. Correspondingly, for a maximum allowable rate of 10 R/min., test values of greater than or equal to 14 R/min. (uncorrected) but less than 25 R/min. are included.

(n) A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 10% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

(o) Intraoral dental systems capable of operations in the above 50 kVp range for which the field size at the cone tip is greater than or equal to nine centimeters or which exhibit a minimum SSD less than 16 centimeters.

(p) Dental radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.

(q) Mammographic x-ray systems in which the edge of the x-ray field at the chest wall extends beyond the edges of the image receptor by more than 5% of the source to image receptor distance.

(r) Therapy systems which fail to maintain proper surveys, calibrations, spot checks or operating procedures.

(2) Transportation.

(a) Breach of package integrity;

(b) Surface contamination or external radiation levels in excess of, but less than a factor of five above Agency requirements that did not result from a breach of package integrity;

(c) Any noncompliance with labeling, placarding, shipping paper, packaging loading, or other requirements that could reasonably result in the following:

a. Improper identification of the type, quantity, or form of material;

b. Failure of the carrier or recipient to exercise adequate controls; or,

c. Substantial potential for personnel exposure or contamination, or improper transfer of material; or,

(d) Failure to make required initial notification associated with Severity Level III violations.

(3) Materials Operations.

(a) Failure to control access to licensed materials for radiation purposes as specified by Agency

requirements;

(b) Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;

(c) Use of radioactive material on humans where such use is not authorized;

(d) Conduct of licensed activities by a technically unqualified person;

(e) Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or,

(f) Medical therapeutic misadministrations.

(g) Failure to obtain appropriate Agency approval before moving to a new use and/or storage location.

(4) Miscellaneous Matters.

(a) An MFS not amounting to a Severity Level I or II violation; or,

(b) Deliberate falsification, or falsification by or with the knowledge of management of records which the Agency requires be kept that did not involve signification information.

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(5) Emergency Preparedness. Violations of lesser severity than Severity Level II violations.

(D) Severity Level IV -- Violations.

(1) Health Physics.

(a) Exposures in excess of the limits of 105 CMR 120.211 not constituting Severity Level I, II, or III violations;

(b) A radiation level in an unrestricted area such that an individual could receive greater than two millirem in a one-hour period or 100 millirem in any seven consecutive days;

(c) Failure to make a 30-day notification required by 105 CMR 120.283;

(d) Failure to make a follow-up written report as required by 105 CMR 120.281, 120.287 and 120.750; or,

(e) Any other matter that has more than minor safety or environmental significance.

(f) A capacitor storage radiographic system such that the standby radiation is greater than 3.0 mR/hr, but less than 25 mR/hr.

(g) Systems equipped with positive beam limiting devices which do not allow the field size to be reduced to a size less than that of the image receptor.

(h) Systems equipped with positive beam limiting devices which do not provide for an automatic return to PBL from a reduced field size.

(i) Mobile radiographic systems for which the minimum source to skin distance is less than 27.5 centimeters.

(j) Mammographic systems manufactured after October 1977 for which the edges of the x-ray field on the right or left sides extend beyond the edges of the image receptor. If manufactured prior to November 1977 and the edges of the x-ray field on either side extend beyond the edge of the image receptor by more than 5% of the SID.

(2) Transportation.

(a) Package selection of preparation requirements which do not result in a breach of package integrity or surface contamination or external radiation levels in excess of Agency requirements; or,

(b) Other violations that have more than minor safety or environmental significance.

(3) Material Operations.

(a) Failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

(b) Other violations that have more than minor safety or environmental significance; or,

(c) Failure to report medical diagnostic misadministrations.

(4) Miscellaneous Matters.

(a) A false statement caused by an inadvertent clerical or similar error involving information which, had it been available to the Agency and accurate at the time the information should have been submitted, would probably not have resulted in regulatory action or the Agency seeking additional information.

(b) Unless specified in a more severe category, changes in procedures or other conditions of a

license or certificate of registration of which the Agency was not informed (*e.g.*, change of address, expiration of certificate of registration); or,

(5) Emergency Preparedness. Violations of lesser severity than Severity Level III violations.

(E) Severity Level V -- Minor Violations.

(1) Health Physics.

(a) For a fluoroscopic x-ray system where the maximum allowable tabletop exposure rate is 5 R/min., test values of greater than 5.0 R/min. (uncorrected), but less than 7.0 R/min. Correspondingly, if the maximum allowable tabletop exposure rate is 10 R/min., test values of greater than 10.0 R/min. (uncorrected) but less than 14.0 R/min. are included.

(b) Other violations that have minor safety or environmental significance.

(2) Transportation. Other violations that have minor safety or environmental significance.

(3) Materials Operations. Other violations that have minor safety or environmental significance.

(4) Miscellaneous Matters. Other violations that have minor safety or environmental significance.

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(5) Emergency Preparedness. Other violations that have minor safety or environmental significance.